



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 5, 2016

Talley Group Ltd.
Mr. Robert Macdonald
Quality and Regulatory Affairs Manager
Premier Way
Abbey Park Industrial Estate
Romsey, Hampshire SO51 9DQ
Great Britain

Re: K143004
Trade/Device Name: Venturi MiNO TG600/14
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 23, 2015
Received: December 7, 2015

Dear Mr. Macdonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Venturi™ MiNO TG600/14

Ref: K143004

510(k) number K143004

Indications for Use

510(k) Number (if known):

Device Name: Venturi™ MiNO TG600/14

Indications for Use:

The Talley Venturi™ MiNO TG600/14 is intended for use for patients with acute or chronic wounds that may be benefitted by the application of continual negative pressure wound therapy to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The device is intended for use by qualified healthcare professionals in a healthcare environment.

Prescription Use **Yes** And/Or Over the Counter Use No

(21 CFR Part 801 Subpart D)

(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary Venturi Mino TG600/14 4th January 2016**510(K) number K143004**

Manufacturer and submitter: Robert Macdonald.
Talley Group, Ltd.
Premier way.
Abbey park industrial estate
Romsey, Hampshire
SO51 9DQ
England.
rmacdonald@talleygroup.com
Phone 0044 1794 503575
Fax 0044 1794 503539

Device name: Venturi™ MiNO TG600/14
Common Name: Negative pressure wound therapy pump
Classification name: Negative pressure wound therapy powered suction pump
Classification code: OMP
Regulation number: 878.4780
Class: 2
Equivalent device 1 Venturi V.II
Talley Group LTD
K090258

Equivalent device 2 Venturi
Talley Group LTD
K080897

There have been no prior submissions (pre-submission, IDE or 510(k)) for the Venturi MiNO TG600/14 Negative Pressure Wound Therapy device.

How the device functions, and scientific concepts that form the basis for the device.

Negative Pressure Wound Therapy (NPWT) is a wound care therapy that uses suction via an electrical pump and a wound dressing.

The significant physical and performance characteristics of the device, such as device design material used and physical properties.

Vacuum Pump Unit: Venturi MiNO NPWT TG600/14
Construction: Flame Retardant ABS
Dimensions / Weight: 105mm x 52mm x 112mm / 290g
Pressure Range: 80mmHg and 120mmHg

Intended Use.

The Talley Venturi™ MiNO TG600/14 is intended for use for patients with acute or chronic wounds that may be benefitted by the application of continual negative pressure wound therapy to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. The device is intended for use by qualified healthcare professionals in a healthcare environment.

A general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate,

For management of chronic, acute, traumatic, subacute and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Substantial equivalence:

All predicate products provide a combination of an electrically powered suction pump and a patient wound dressing kit, sealed with a clear dressing over the wound, and a tubing connection set to attach the sealed dressing to the suction pump for fluid removal. All predicate devices also include a single-patient-use fluid collection vessel (canister) for containment and disposal of evacuated fluids. The consumable dressing kit items are widely available on the market and packaged with the powered suction pumps as a convenience to the clinical users of the device. Talley believes this information supports substantial equivalence of the Venturi™ MiNO to the predicate devices.

If the determination of substantial equivalence is also based on an assessment of non-clinical performance data, the summary includes a brief discussion of the nonclinical tests submitted

The performance testing of the pump with the predicates that shows the performance is comparable to the predicates

Canister vacuum test is performed on 100% of production units to check for air-tightness and recognition of sensor pins. Loss of vacuum is measured over a prescribed period.

Vacuum pump test is performed on 100% of production sub-assemblies measuring flow and pressure, ensuring 120mmHg is achieved.

Tested levels are compared with defined minimum values to determine pass or fail.

Soak test is performed on 100% of assembled production pump units and are run for 48 hours prior to final test to confirm vacuum pressure levels.

Final system test is performed on 100% of production units. Tests include all functions and buttons, correct pressure calibration, air tightness, canister recognition, warning systems / alarms and that the charging system operational.

If the determination of substantial equivalence is also based on an assessment of clinical performance data

Substantial equivalence is based on an assessment of non-clinical performance data and no clinical performance data is included.

Conclusion

The working pressures, non-clinical tests, alarm functions, general concept and intended use supports substantial equivalence of the Venturi™ Mino Vacuum System to the predicate devices. The Venturi MiNO TG600/14 is substantially equivalent to the predicate devices non-clinical tests demonstrates that the device is as safe, as effective, and performs as well as or better than the predicate devices.